

## **REMARKS**

Reconsideration of the above referenced application is respectfully requested. Upon entry of the foregoing amendment, Claims 61-77 and 79-97 are presently pending. Claims 65-66 and 74-75 have been withdrawn. Claims 68, 77 and 97 have been amended. Claims 1-60, 78 and 98 have been cancelled without prejudice or disclaimer. Applicants reserve the right to pursue the subject matter of the cancelled claims in one or more continuation or divisional application. No new matter has been introduced and entry of the amendment is requested.

### **Rejections under 35 U.S.C. §112, second paragraph**

Claims 68, 77, 78, 97 and 98 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 68 has been amended to correct the claim dependency.

Claims 77 and 97 have been amended to make reference to the PSA promoter and enhancer sequence presented as SEQ ID NO:1.

Claims 78 and 98 have been cancelled here in obviating the basis for rejection.

Applicants respectfully submit that the grounds for the rejection have been obviated by the amendments submitted herein. Withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

### **Rejections under 35 U.S.C. §102**

Claims 61-64, 67, 72, 73, and 76 stand rejected under 35 U.S.C. §102(e) as being anticipated by Gregory et al. for the reason set forth on page 7 of the Office Action.

Gregory et al. allegedly discloses replication competent adenoviral vectors comprising a gene essential for replication under operative control of a disease specific transcriptional regulatory sequence. Gregory *et al.*, provides a method for “amplifying the effect of the therapeutic gene carried by the replication competent adenoviral vector”. In contrast to the present claims, Gregory et al. is directed to disease specific replication competent adenoviruses for use in gene therapy, which necessarily include therapeutic genes (therapeutic or cytotoxic genes). As defined by Gregory *et al.*, therapeutic genes are foreign genes expressed from the

replication competent adenoviral vectors, and specifically are not present in wild-type adenovirus. It follows that Gregory et al. is directed to targeted gene therapy for treatment of cancer using an adenovirus vector comprising a disease specific regulatory region, wherein the vector serves as a gene delivery vehicle.

For anticipation under 35 U.S.C. §102, the reference “must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present.” (MPEP §706.02). “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” Verdegaal Bros. v. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Gregory et al. lacks explicit description of the structural features of the invention as required for anticipation under 35 U.S.C. § 102(e).

Claims 61 and 62 stand rejected under 35 U.S.C. §102(b) as being anticipated by Hallenbeck et al. for the reason set forth on pages 7 and 8 of the Office Action.

Hallenbeck et al. allegedly discloses replication conditional adenovirus vectors designed to limit replication to specific cell types by linking an adenoviral gene to any one of a number of different tissue or tumor-specific promoters. The reference lack explicit disclosure of a method for selective cytolysis of a target cell, by contacting the target cell with an adenovirus vector comprising a cell type-specific transcriptional regulatory element (TRE), as presently claimed.

Hallenbeck et al. lacks explicit description of every aspect of the claimed invention. Accordingly, the rejection under 35 U.S.C. § 102(e) should be withdrawn.

### **Rejections under 35 U.S.C. §103**

Claims 61, 64, 67, and 68 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gregory et al. (3) taken with Srivastava (US 5,252,479) for the reason set forth on page 9 of the Office Action..

To establish a *prima facie* case of obviousness the prior art reference (or references when combined) must teach or suggest all of the claim limitations. In re Vaeck, 20 USPQ2d 1438 (Fed. Cir. 1991) and MPEP § 2142. Moreover, when applying 35 U.S.C. § 103, the following tenets of patent law must be adhered to: (A) The claimed invention must be considered as a whole; (B) The references must be considered as a whole and must suggest the desirability and

thus the obviousness of making the combination; (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (D) Reasonable expectation of success is the standard with which obviousness is determined. Hodosh v. Block Drug Co., Inc., 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

As set forth above, is directed to targeted gene therapy for treatment of cancer using an adenovirus vector comprising a disease specific regulatory region, wherein the vector serves as a gene delivery vehicle. Srivastava (US 5,252,479) does not make up for the lack of disclosure in Gregory et al.

It follows that the Examiner has not made a prima facie case of obviousness and the rejection under 35 USC § 103(a) should be withdrawn.

#### **Double Patenting Rejection**

Claims 61, 62, 63, 72, 76 and 77 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 5,698,443.

Applicants respectfully submit that the present claims are not obvious in view of the claims of the cited patent. However, in order to further prosecution, filing of a terminal disclaimer will be considered upon indication of otherwise allowable subject matter.

Claims 61, 62, 63, 64, 72, 76, 79, 81, 83, 84, 89, 92, 93, and 96 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10 and 29-31 of U.S. Patent No. 6,676,935.

Applicants respectfully submit that the present claims are not obvious in view of the claims of the cited patent. However, in order to further prosecution, filing of a terminal disclaimer will be considered upon indication of otherwise allowable subject matter.

Claims 61, 62, 69-71, 79, and 89-91 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17-20, 30-32, 44-48, and 51-54 of U.S. Patent No. 6,197,293.

Applicants respectfully submit that the present claims are not obvious in view of the claims of the cited patent. However, in order to further prosecution, filing of a terminal disclaimer will be considered upon indication of otherwise allowable subject matter.

Claims 61, 62, 79, 80, 82 and 92-95 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15, 16, 24, and 25 of U.S. Patent No. 6,436,394.

Applicants respectfully submit that the present claims are not obvious in view of the claims of the cited patent. However, in order to further prosecution, filing of a terminal disclaimer will be considered upon indication of otherwise allowable subject matter.

Claims 61 and 62 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 7,011,976.

Applicants respectfully submit that the present claims are not obvious in view of the claims of the cited patent. However, in order to further prosecution, filing of a terminal disclaimer will be considered upon indication of otherwise allowable subject matter.

Claims 61, 62, and 69-71 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 34-63 of U.S. Patent No. 6,254,862.

Applicants respectfully submit that the present claims are not obvious in view of the claims of the cited patent. However, in order to further prosecution, filing of a terminal disclaimer will be considered upon indication of otherwise allowable subject matter.

Claims 61 and 62 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 21 of U.S. Patent No. 6,585,968.

Applicants respectfully submit that the present claims are not obvious in view of the claims of the cited patent. However, in order to further prosecution, filing of a terminal disclaimer will be considered upon indication of otherwise allowable subject matter.

Claims 61, 62, 64, 67-69, 71, 79, 81, 82, 84, 87-89 and 91 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 8-15, and 17-19 of U.S. Patent No. 6,991,935.

Applicants respectfully submit that the present claims are not obvious in view of the claims of the cited patent. However, in order to further prosecution, filing of a terminal disclaimer will be considered upon indication of otherwise allowable subject matter.

Claims 61-63, 73, and 76-78 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-32 of U.S. Patent No. 5,871,726.

Applicants respectfully submit that the present claims are not obvious in view of the claims of the cited patent. However, in order to further prosecution, filing of a terminal disclaimer will be considered upon indication of otherwise allowable subject matter.

Claims 61, 62, and 79 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 82-89 of copending Application No. 11/267,275.

Applicants respectfully submit that the present claims are not obvious in view of the claims of the cited application. However, in order to further prosecution, filing of a terminal disclaimer will be considered upon indication of otherwise allowable subject matter.

Claims 61 and 62 stand rejected as not patentably distinct from claim 21 of commonly assigned U.S. Patent No. 6,585,968.

Claims 61 and 62 stand rejected as not patentably distinct from claims 17-20, 30-32, 44-48, 51-54 of commonly assigned U.S. Patent No. 6,197,293.

Claims 61 and 62 stand rejected as not patentably distinct from claims 1-10 of commonly assigned U.S. Patent No. 7,011,976.

Claims 61, 62, 79, 80, 82, and 92-95 stand rejected as not patentably distinct from claims 15, 16, and 24-25 of commonly assigned U.S. Patent No. 6,436,394.

Claims 61, 62, and 69-71 stand rejected as not patentably distinct from claims 34-63 of commonly assigned U.S. Patent No. 6,254,862.

Claims 61, 62, 64, 67-69, 71, 79, 81, 82, 84, 87-89 and 91 stand rejected as not patentably distinct from claims 1-4, 8-15, and 17-19 of commonly assigned U.S. Patent No. 6,991,935.

Applicant respectfully submits that all of the cited patents and the subject application were, at the time the subject application was filed, owned by and subject to an obligation of assignment to, the same entity, Cell Genesys Inc.

More specifically, U.S. Paten Nos. 6,585,968; 6,197,293; 7,011,976; 6,436,394; 6,254,862; and 6,991,935 were, at the time the invention of U.S. Application No. 10/913,976 was made, originally owned by Calydon, Inc., recorded December 17, 201 (Reel/Frame # 009334/0703), followed by a blanket assignment of Calydon Inc. applications and patents to Cell Genesys, Inc, recorded December 17, 201 (Reel/Frame # 012243/0012)

The above statements are sufficient to invoke 35 USC §103(c), pursuant to MPEP §706.02(l)(2).

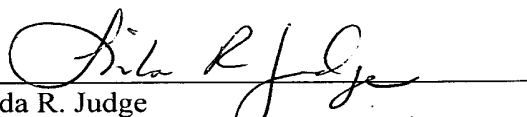
## CONCLUSION

Applicants submit that the application is now in condition for examination on the merits. Early notification of such action is earnestly solicited. If any issues remain which the Examiner feels may be best resolved through a personal or telephonic interview, the Examiner is respectfully requested to contact Applicants counsel, Linda R. Judge at (415) 836-2586.

Respectfully submitted,

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